

JUL 30 2003

K 03/987

SECTION 17: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

17.1: ADMINISTRATIVE INFORMATION

Name and Address

Submitted by: Cardiac Science Incorporated
5474 Feltl Road
Minnetonka, MN 55343

Contact Person: Kenneth F. Olson
Telephone No.: 952-939-4181
Facsimile No.: 952-939-4191
Email: kolson@cardiacscience.com

Date Prepared: June 25, 2003

17.2: DEVICE INFORMATION

Common or Usual Name: Automatic External Defibrillator

Trade Name: Powerheart® Automatic External Defibrillator G3
Model 9300

17.3: DEVICE CLASSIFICATION

Classification Name: Automatic External Defibrillator
21 CFR 870.1025 MKJ
Device Class: III

17.4: DEVICE DESCRIPTION

The Powerheart® AED G3 is a portable, battery-operated, semi-automatic, low power DC defibrillator. The device is designed to diagnose and monitor the patient's cardiac rhythm and advise the operator if and when to deliver the shock energy. The Powerheart® AED device in this submission is identical to the current Powerheart® AED and accessories in commercial distribution that was cleared under premarket 510(k) notifications K022929, K011901 and K982710. The reason for this premarket notification is to introduce minor modifications to the device and upgrade software.

17.5: INDICATION FOR USE

The Powerheart® AED G3 is intended to be used by personnel who have been trained in its operation. The user should be qualified by training in basic life support or other physician-authorized emergency medical response.

The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Post-resuscitation, if the victim is breathing, the AED should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver therapy.

When the patient is a child or infant up to 8 years of age, or up to 55 lbs (25kg), the Powerheart® AED G3 should be used with the Model 9730 Pediatric Attenuated Defibrillation Electrodes. The therapy should not be delayed to determine the patient's exact age or weight.

17.6: IDENTIFICATION OF PREDICATE DEVICE

<u>Company</u>	<u>Device</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
Cardiac Science	Powerheart AED	K022929	01/27/2003
Survivalink	FirstSave Biphasic AED	K011901	02/01/2002
Corporation (Cardiac Science)	(renamed Powerheart AED)	K982264	01/25/1999

17.7: SUBSTANTIAL EQUIVALENCE

The Powerheart® AED G3, Model 9300 covered by this submission is substantially equivalent to other legally marketed automatic external defibrillators. Specifically, the Powerheart® AED G3 that is the subject of this premarket notification is identical to current Powerheart® AED in commercial distribution with the exception of minor device modifications to the hardware and software. The device modifications do not raise any new issues of safety or effectiveness.

17.8 PERFORMANCE TESTING

The Powerheart® AED G3 was subjected to performance hardware and software evaluations in accordance with FDA guidelines and industry standards. The results of the testing showed that the device modifications had no affect on the safety or effectiveness of the device. The Powerheart® AED G3 passed all software and hardware tests and was found to perform as intended.

17.9 CONCLUSIONS

Cardiac Science has demonstrated through its evaluation and testing of the Powerheart® AED G3, Model 9300, that the device with minor modifications is equivalent to the current Powerheart® AED. The proposed Powerheart® AED G3 is identical with respect to indications for use, technological characteristics, materials, function and software algorithm as the current commercially distributed Powerheart® AED. This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2003

Cardiac Science, Inc.
Minneapolis Operations
c/o Mr. Kenneth Olson
Chief Technical Officer
5474 Feltl Rd.
Minneapolis, MN 55343

Re: K031987
PowerHeart AED G3, Model 9300
Regulation Number: 870.1025
Regulation Name: Arrhythmia Defector and Alarm
Regulatory Class: Class III
Product Code: MKJ
Dated: July 18, 2003
Received: July 21, 2003

Dear Mr. Olson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

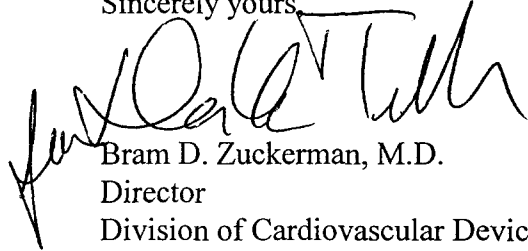
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over the typed name.

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

INDICATIONS FOR USE

510(k) Number:

Device Name: Powerheart® Automatic External Defibrillator G3
Model 9300

Indications for Use: The Powerheart® AED G3 is intended to be used by personnel who have been trained in its operation. The user should be qualified by training in basic life support or other physician-authorized emergency medical response.

The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Post-resuscitation, if the victim is breathing, the AED should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver therapy.

When a patient is a child or infant up to 8 years of age, or up to 55 lbs (25kg), the Powerheart AED G3 should be used with the Model 9730 Pediatric Attenuated Defibrillation Electrodes. The therapy should not be delayed to determine the patient's exact age or weight.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐


(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number

K031987